REMARKS

Reconsideration and withdrawal of the rejections of the claimed invention is respectfully requested in view of the amendments, remarks and enclosures herewith, which place the application in condition for allowance.

I. STATUS OF CLAIMS AND FORMAL MATTERS

Claims 1-14 are still pending in this application. No new matter has been added by this amendment.

It is submitted that the claims, herewith and as originally presented, are patentably distinct over the prior art cited in the Office Action, and that these claims were in full compliance with the requirements of 35 U.S.C. § 112.

II. THE 35 U.S.C. 103(a) REJECTION HAS BEEN OVERCOME

Claims 1-14 were rejected as allegedly being obvious by Nara et al. (US 6,245,351 - "Nara") in view of Rupprecht et al. (DE 101 46 251 - "Rupprecht"). The applicants request reconsideration of this rejection for the following reasons.

Background

Although the rejection has been modified to a combination of Nara and Rupprecht, the rejection is similar to the previous rejection of Nara in combination with Horstmann previously presented.

As such, the applicants will first rebut the "Response to Arguments" section on page 2 of the Office Action. Should this response be deemed not to overcome the rejection by itself, the applicants request consideration of their rebuttal in combination with their revised arguments against the combination of Nara and Rupprecht which follows afterwards.

Rebuttal to "Response to Arguments" section on page 2 of Office Action

While the Examiner is certainly not limited to reciting case law from Appendix II (List of Decisions Cited) of the MPEP, the applicants note that *In re Stover*, 146 F.2d 299, 56 USPQ 525 (CCPA 1944) is not among the decisions cited in Appendix II.[1]

Furthermore, MPEP 2144.04 states in part that "...if the facts in a prior legal decision are sufficiently similar to those in an application under examination, the examiner may use the rationale used by the court."

Stover was relied upon for the proposition that "...it is a matter of choice and not inventions (sic) to select any particular shape desired in the finished product." (see last three lines on page 2 of the Office Action). The applicants note that case law with regard to design changes, shapes and sizes are often in the context of the mechanical arts or related to devices and *Stover* is no different.

The claims in *Stover* related to an elongated paper container particularly adapted for receiving and packaging ice cream, or other plastic foodstuffs, for subsequent sale to the public in sanitary and predetermined units. *Id.* @ 300.

The Board in *Stover* "...decide that it would not amount to invention to provide the container of Clearwater with the markings as taught by Tiffany, and with the vents or openings for the escape of air as taught by Ortner or Massey, and that no patentable conception is involved in filling a container through the urge of gravity, as that procedure is but a common expedient for filling containers with a liquid or semiliquid substance. The rejected claims herein cover an article, the construction of which, in view of the prior art, would be within the obvious and expected routine skill of those laboring in the art, and are, therefore, unpatentable." *Id.* @ 301-302.

Regardless of whether the decision in *Stover* would have withstood the scrutiny of the standards for obviousness set forth in 35 U.S.C. 103 introduced eight years later in the Patent Act of 1952, the facts of *Stover* do not resemble the facts of the presently claimed application.

Unlike the design choice for a mechanical device in *Stover*, the Examiner here is attempting to provide an equivalency for all forms of pharmaceutical dosage forms which would be unrecognizable to those of ordinary skill in the pharmaceutical arts.

Whole industries have been built on selecting and developing a specific form of drug delivery methods and as such one of ordinary skill in the art concerned with the formation of enteric capsules as in Nara would not use the teachings of Rupprecht (or any other film forming prior art) as this does not assist in the production of a completely different pharmaceutical dosage delivery form (i.e. capsule vs. film).[2]

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[1] And also predates the Patent Act of 1952, i.e. prior to the establishment of 35 U.S.C. 103.

[2] By way of example, the applicants provide the table of contents from *Ansel's Pharmaceutical Dosage Forms and Drug Delivery Systems (Eighth Edition)*, Allen et al., Lippincott Williams & Wilkins (2005).

The differences in pharmaceutical dosage delivery forms is also recognized by the PTO's classification system, Class 424, subclass 400 (Preparations Characterized by Special Physical Form), Class 424, subclass 451+ (Capsules), Class 424, subclass 484 (Matrices). The applicants do not suggest that prior art from differing classes can never be used in combination, but for the presently claimed invention, the modifications required to be made for the combination of Nara and Rupprecht would not be obvious to one of ordinary skill in the art as their respective pharmaceutical dosage forms are so vastly different; one of ordinary skill in the art would not be able to magically select a single element from one reference (or even look to the reference) for combination with the other reference to arrive at the applicants' claimed film form with regard to the product claims (claims 5-9 and 14) and certainly not for the process claims of making the film form (claims 1-4 and 10-13).

Arguments against the combination of Nara and Rupprecht establishing a *prima facie* holding of obviousness

The rejection of the pending claims shows the traps associated when prior art is apparently relied upon for their hits of selected keyword terms without considering the context of the reference or the applicants' claimed invention.

While the Office Action identified features of the applicants' invention and partially identified the differences between the claimed invention and the teachings of Nara, the applicants' claimed invention and the Nara and Rupprecht references did not appear to be considered as a whole as is required when making a determination of obviousness. *See MPEP 2141.02.*

First, the difference between Nara and the claimed invention is not limited merely to the step of drying the mixture or that the dosage is in film form for surface/topical adminstration (which are substantial differences in and of themselves), but also includes the additional differences that:

(1) the hydrophilic polymers crosslinked with at least one polyacrylic acid derivative (and for the claims as amended, the hydrophilic polymers are crosslinked by the polyacrylic acid derivative *in situ*)[3]; and

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[3] Moreover, there appeared to be a misunderstanding in the Office Action about the teaching within Nara about crosslinking. The liquid coating composition used by Nara comprises of a water-insoluble substance, swellable

(2) there is no mention of the simultaneous spraying of an aqueous solution of the hydrophilic polymers and aqueous solution of the polyacrylic acid derivative.

Nara also differs from the applicants' claimed invention in that their method for producing their unrelated composition does so in a manner which teaches away from either Rupprecht or the applicants' claimed process. Nara prepares a drug-containing core following by spray-coating the resulting core with a liquid coating composition; for illustrative purposes see Example 3 (col. 9, lines 8-13) and Example 7 (col. 10. lines 43-48) – "These core granules were placed in a spiral flow type coating machine and spray coated with hydroxypropylmethylcellulose dissolved in a mixture of ethanol and water…to yield coated granules.".

What Nara is teaching is an active agent in an inner core which is an element not taught in Rupprecht or in the applicants' claimed invention and Nara does not suggest the active agent being in anything which would be considered equivalent to a film.

As Rupprecht does not address these differences, the combination of Nara and Rupprecht do not render the applicants' claims for this reason alone as all claim elements are not taught or suggested by the combination of Nara and Rupprecht. Moreover, in the context of Nara's invention, it would be nonsensical to place the active ingredient in a film which coats Nara's inner core as this film is destroyed in providing the enteric effect in allowing the composition to pass through the stomach acidic environment and would only serve to waste valuable active ingredient.

In addition, even if Rupprecht had taught all the missing elements, when considering Nara as a whole, it is not even related to the type of dosage forms which is taught both by the applicants' claimed invention and by Rupprecht (i.e. film forms). Nara refers to an alternative form of an ***enteric*** capsule consisting of a drug core with an outer coating which is clearly identified in the "Summary of the Invention" (see col. 1, lines 50-57 – "…to develop a controlled-release composition for ***oral administration*** coated with a coating composition which is capable of releasing drug at higher rates in the ***intestinal tract*** than in the stomach to maintain an almost constant plasma concentration of drug and ensure effect of drug in the body for an extended period of time.")

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polymer and an ***already crosslinked polymer***, i.e. the swellable polymer is ***not crosslinked*** to the crosslinked polymer.

In contrast, Rupprecht is directed to a device for making films and only generically refers to the film making process which is completely different than the controlled-release compositions of Nara. Even if one of ordinary skill in the art were permitted to pick and choose elements from the combination of Nara and Rupprecht at will, the skilled artisan still would not achieve the applicants' claimed process steps of claims 1-4 and 10-13, nor would they obtain the products formed by the process.

Moreover, one of ordinary skill in the art would not look to use Rupprechts' device to make modifications to the invention of Nara, given the differences in forms, as there is no expectation of success that taking an isolated element from Rupprecht could be incorporated into the controlled-release composition of Nara while maintaining the intended use of Nara, i.e. releasing drug at higher rates in the ***intestinal tract*** than in the stomach to maintain an almost constant plasma concentration of drug.

Therefore, it would not have been obvious to combine Rupprecht with Nara as there was no reason to combine teachings from disparate inventions nor was there a reasonable expectation of success for the combination proffered in the Office Action.

CONCLUSION

In view of the remarks and amendments herewith, the application is believed to be in condition for allowance. Favorable reconsideration of the application and prompt issuance of a Notice of Allowance are earnestly solicited. The undersigned looks forward to hearing favorably from the Examiner at an early date, and, the Examiner is invited to telephonically contact the undersigned to advance prosecution. The Commission is authorized to charge any fee occasioned by this paper, or credit any overpayment of such fees, to Deposit Account No. 50-0320.

Respectfully submitted,
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Ansel's Pharmaceutical Dosage Forms and Drug Delivery Systems

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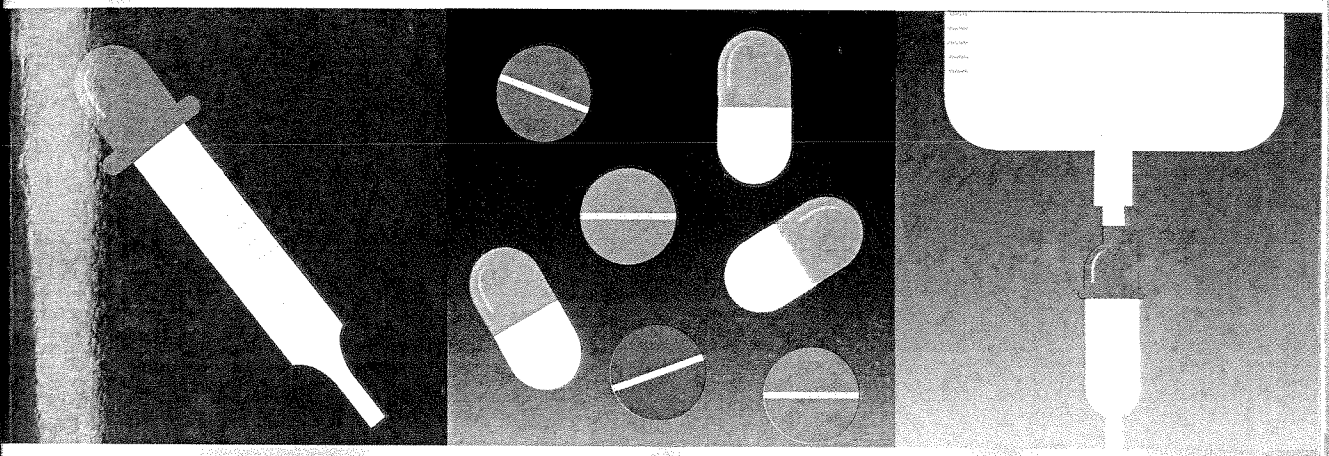

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